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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/559,355	04/27/2000	Ralf Zink	8265-320	2908

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EXAMINER
WARE, DEBORAH K

ART UNIT	PAPER NUMBER
1651	9

DATE MAILED: 12/10/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/559,355	Applicant(s) Zink et al.
	Examiner Ware, D.	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 10-5-01.

2a)☐ This action is **FINAL**. 2b)☑ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) 12-17 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) 1-11 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☑ All b)☐ Some * c)☐ None of:

1.☑ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) #4.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 1-17 are pending.

The Information Disclosure Statement filed April 27, 2000, has been received and the references submitted therewith have been considered as indicated on the enclosed PTO-1449 Form.

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Therefore, Applicants' foreign priority has been acknowledged.

2. Applicant's election without traverse of Group I, claims 1-11, in Paper No. 8 is acknowledged.

3. Claims 12-17 are withdrawn from further consideration pursuant to 37 CAR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

Claims 1-11 are examined on the merits as follows:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the microorganism strains disclosed in the specification (note page 10 of the instantly filed specification) are required to grow the *Lactobacilli* and the whole genus of *Lactobacilli* recited in each of the claims, the strains appear to be essential to the whole invention as recited in those claims. It must therefore be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not apparent if the microorganism is readily available to the public.

It is noted, however, that applicants have deposited the organisms but there is no indication in the specification as to public availability of the strains, with the exception of ATCC 11506. Therefore, the following guidelines are set forth for the assurance of public availability of the other strains disclosed in the specification for culturing of the claimed *Lactobacilli.*

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

(d) the deposit will be replaced if it should ever become inviable.

Applicant is directed to 37 CAR § 1.807(b) which states:

(b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:
(1) The name and address of the depository;
(2) The name and address of the depositor;
(3) The date of deposit;
(4) The identity of the deposit and the accession number given by the depository;
(5) The date of the viability test;
(6) The procedures used to obtain a sample if the test is not done by the depository; and
(7) A statement that the deposit is capable of reproduction.

Applicant is also directed to 37 CAR § 1.809(d) which states:

(d) For each deposit made pursuant to these regulations, the specification shall contain:

(1) The accession number for the deposit;
(2) The date of the deposit;
(3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and
(4) The name and address of the depository.

4. Further, claim 5 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

5. Claim 5 is not clearly supported and described in the instantly filed specification for the amount of iron added in the range of about 10 to about 200 milligrams of iron per liter of medium.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2, 3, 4, 5, 6, 8, 9, 10, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 5 lack antecedent basis for the recitation of "of medium" at bridging lines 2-3. The language should be changed to --of said medium-- .

Claims 3-4 lack antecedent basis for the recitation of "the amino acids" at lines 2-3 of claim 3. The language should be changed to --the at least four amino acids" in claim 3.

Claim 6 is also rejected for the reasons noted above for claims 2 and 3, for the language "the amino acids" at line 1 and "of medium" recited at line 3.

Claim 8 is rendered vague and indefinite for the improper recitation of Markush type language wherein the terminology "or mixtures thereof" should be changed to --and mixtures thereof--.

Claim 9 is rendered vague and indefinite for being confusing for the recitation of the clause "wherein the ribonucleotide precursors comprise free bases" since the claim is directed to a further limitation regarding "added magnesium and aspartic acid" ? Thus, it is unclear why the clause at the end is necessary and it makes the claim confusing with respect to what is intended by the free bases as a defining limitation for the ribonucleotide precursors. Therefore, the deletion of the clause or at least the addition of --and-- before "wherein" at line 2 of claim 9 is requested.

Claim 10 recites "the amino acids" at line 1. This phrase is rejected for those reasons noted above. The same change to remedy the rejection is requested. Also the recitation of "of medium" after each "per liter" amount described in the claim should be remedied as described above. Further, at the end of the claim the "wherein" clause regarding "the amount of iron in the additive system is sufficient to add about 10 to about 200 milligrams of iron per liter of medium" is inconsistently described with respect to the format used to define other "added" components of the "additive system". Thus, it is suggested to change the terminology as follows:

--and wherein the iron added is in the range of from about 10 to about 200 milligrams per liter of said medium-- .

Claim 11 is rendered vague and indefinite for the recitation of "UHT milk" and also for the clause "whether prepared from natural sources or from dried milk powder by addition of water" is intended to include all of the milk-derived bases described. Thus, it is suggested to insert --said milk-derived base is-- before "prepared" at line 2. Also it is suggested to spell out the abbreviation "UHT" in the claim.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gil et al. (A) in view of Hata (AC), note enclosed PTO-892 and PTO-1449 Forms.

Claims drawn to a medium composition comprising a milk base and added amino acids, ribonucleotide precursors and iron sufficient to promote growth of *Lactobacilli.*

Gil teaches ribonucleotides (i.e. uracil, cytidine, uridine, adenosine, guanosine) and iron as constituents of a composition, note column 9, all lines and the abstract.

Hata teaches added cysteine, isoleucine, serine and alanine as well as aspartic acid in a medium composition. Note columns 13-14, all lines.

The claimed subject matter differs from Gil in that cysteine, isoleucine, alanine, serine and aspartic acid are not clearly disclosed.

It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to provide for a medium composition as disclosed by Gil et al. and added thereto the amino acids disclosed by Hata for growing Lactobacilli. Clearly one of skill in the art would have expected successful results with the addition of other amino acids thereto. To further include other ingredients to the composition of Gil is an obvious modification in the art. The amino acids disclosed by Hata are clearly taught to be useful for growing Lactobacilli. Clearly one of skill would have been motivated to combine these ingredients in a medium composition for growing Lactobacilli. To vary the amounts of each of these ingredients is clearly within the purview of an ordinary artisan. The claims are prima facie obvious over the cited prior art.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 7-8 and 11 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gil et al., discussed above.

Claims are discussed above.

The cited reference clearly teaches the UHT milk base, added antioxidant and additive system of at least four amino acids, iron, and at least two ribonucleotides. The claims are very similar to the disclosure of Gil and are, therefore, considered to be anticipated by the teachings thereof. However, in the alternative that there is some unidentified claimed characteristic that provides for some difference then such difference is considered to be so slight as to render the claims alternatively prima facie obvious over the cited reference alone.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is (703) 308-4245. The examiner can normally be reached on Mondays to Fridays from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Deborah K. Ware

DEBORAH K. WARE
PATENT EXAMINER

Deborah K. Ware

Art Unit 1651

December 15, 2001